IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, *ex rel.* [UNDER SEAL], Plaintiff, v. [UNDER SEAL], Defendant.	NO. **2:17-cv-00395-RMP** COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 *et seq.* DEMAND FOR TRIAL BY JURY

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, *ex rel.* UPPI, LLC, Plaintiff, v. TRILLAMED, LLC and PETNET SOLUTIONS, INC., Defendants.	NO. COMPLAINT AND DEMAND FOR TRIAL BY JURY

COMES NOW, UPPI, LLC ("UPPI" or "Relator"), through the undersigned attorneys, on behalf of the United States of America, and files this *qui tam* Complaint against Defendants TrillaMed, LLC ("TrillaMed") and PETNET Solutions Inc. ("PETNET") (collectively "Defendants") and alleges as follows:

I. INTRODUCTION

1. UPPI brings this action on behalf of the United States of America against Defendants to recover civil penalties, damages, attorneys' fees, and costs as a result of Defendants' violations of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA").

2. In particular, TrillaMed has defrauded the United States by using its status as a Service Disabled Veteran-Owned Small Business Concern (referred to interchangeably as either "SDVOSB" or "SDVO SBC") to bid on, win, and submit claims on Government contracts that were designated as "Small Business Set-Asides," and/or awarded preferentially based on the owner's status as a veteran, service disabled veteran, and/or small business owner. These contracts included, among others, contracts awarded by the United States Department of Veterans Affairs ("VA") and other Government agencies, for nuclear pharmaceuticals (or "radiopharmaceuticals"), which TrillaMed did not perform, was not licensed to perform, and, in fact, could not have performed (and cannot perform) in accordance with the Veterans Benefit Act of 2003 and the Small Business Set Aside Program for SDVOSBs.

3. PETNET Solutions, Inc., which is a wholly-owned subsidiary of Siemens Medical Solutions USA, Inc., and not a SDVOSB, defrauded the United States by using TrillaMed to obtain contracts under false and fraudulent pretenses,

including that TrillaMed was the applicant/bidder; that TrillaMed was licensed to perform contracts for the provision of nuclear pharmaceuticals; and that TrillaMed had complied with the requirements governing the Small Business Set Aside Program for SDVOSBs when bidding on, winning, and submitting claims for reimbursement under these Government contracts.

4. TrillaMed and PETNET entered into an agreement whereby TrillaMed, as a SDVOSB, would bid on contracts for radiopharmaceuticals; PETNET, which was not eligible to bid as an SDVOSB would perform the contracts; and TrillaMed would submit the claims for payment to the Government as if it had performed the contracts, including by falsely and fraudulently certifying that TrillaMed had complied with the regulations governing the handling of nuclear pharmaceuticals, and that TrillaMed had complied with the regulations governing the performance of the SDVOSB Set Aside Program, while omitting that the contract had been principally, if not wholly, performed by PETNET, in violation of these regulations, which certifications were material to the Government's decisions to award and to pay TrillaMed for the contracts.

5. In exchange for using its SDVOSB status to obtain contracts for and on behalf of PETNET, and for submitting the claims for reimbursement to the Government, TrillaMed retained an agreed upon percentage of the proceeds.

6. In exchange for performing the contracts that it was barred from obtaining and performing, PETNET received the rest of the proceeds.

7. Defendants knowingly made, used, and caused to be made or used, false records and statements that were material to the Government's decisions to award the contracts to TrillaMed, in that, *inter alia*, TrillaMed falsely certified and PETNET caused to be falsely certified, that TrillaMed was the applicant/bidder on the contracts, that TrillaMed could and did perform the contracts, and, in particular, that TrillaMed was licensed to perform the contracts, when, in fact, TrillaMed was applying/bidding on the contracts for and on behalf of PETNET; the contracts were to be performed by PETNET; and TrillaMed was not licensed to handle nuclear pharmaceuticals, all in violation of 31 U.S.C. § 3729(a)(1)(B).

8. Defendants further conspired to submit and caused to be submitted false and fraudulent claims for reimbursement, and to make, use, and cause to be made and used false records and statements that were material to the Government's decision to pay the claims, *to wit,* that TrillaMed had performed the contracts as required by and in compliance with the SDVOSB Set Aside Program and other federal regulations, including regulations governing the safety and handling of nuclear materials, when, in fact, the contracts were performed by PETNET, which is a subsidiary in a network that is part of one of the largest companies in the world, all in violation of 31 U.S.C. § 3729(a)(1)(C) .

9. Defendants are jointly and severally liable for civil penalties consistent with the FCA and other provisions, plus three times the amount of the damages which the Government sustained as a result of the violations. 31 U.S.C. § 3729(a)(1)(G).

10. Relator is entitled to between 15-25% of the proceeds that result from this action or any settlement of the claims raised or identified herein. 31 U.S.C. § 3730(d)(1) or between 25 – 35% of the proceeds pursuant to 31 U.S.C. §3730(d)(2).

II. PARTIES

11. Relator UPPI is a membership organization and limited liability company, organized under the laws of the State of Delaware, and having, at all times relevant to this action, its principal place of business in Suwanee, Georgia. UPPI promotes the business interests and manages the growth of its approximately eighty-seven (87) Members, who are individual, small business, and university-based nuclear pharmacies engaged in the manufacturing, production, marketing, sales, and distribution of nuclear pharmaceuticals, including positron emission tomography ("PET") radiopharmaceuticals, and in particular non-HEU (Highly Enriched Uranium) medical isotopes in accordance with the American Medical Production Isotopes Act, 42 U.S.C. § 2065.

12. Defendant TrillaMed is a limited liability company engaged in providing medical materiel and supplies to the United States Government and

organized under the laws of the State of Michigan having, at all times relevant to this action, its principal place of business in Bingham Farms, Michigan. TrillaMed may be served with process through its registered agent for service of process, Frank Campanaro, 30100 Telegraph Road, Suite 366, Bingham Farms, Michigan 48025. TrillaMed is also registered to do business in the State of Washington.

13. TrillaMed describes itself on its website as a SDVOSB that is "operated, managed and owned by three combat veterans who served as U.S. Army Airborne Rangers," and that "specializes in providing world-class medical materiel and MRO (Maintenance, Repair and Operating) supplies to the Department of Veterans Affairs ("VA"), Department of Defense ("DOD") and other Government agencies." The website explains, in effect, that TrillaMed moved from planning to win a federal construction contract to build a hospital, to building a hospital and later, invited by its federal clients and industry leaders, to serve inside the structures they helped build, and, that, as a result of its performance in these areas, had been encouraged to include medical servicing among the services it provides. In particular, TrillaMed advertises that it serves and distributes products to over 700 U.S. Federal Government facilities worldwide, including the VA, DOD, and other Government agencies.

14. TrillaMed has obtained more than five hundred contract awards under the SDVOSB Set Aside program. TrillaMed has performed multiple SDVOSB

contracts in the State of Washington for the VA Medical Center located at 4815 North Assembly Street, Spokane, Washington 99205.

15. Defendant PETNET is a corporation organized under the laws of the State of Tennessee having, at all times relevant to this action, its principal place of business in Knoxville, Tennessee. PETNET may be served with process through its registered agent for service of process, C T Corporation System, 800 South Gay Street, Knoxville, Tennessee 37939-9710. PETNET is also registered to do business in the State of Washington and has a location in the State of Washington listed as 7011 West Flightline Boulevard, Spokane, Washington 99224.

16. Defendant PETNET is a wholly-owned subsidiary of Siemens Medical Solutions, USA, Inc. and is part of the network of companies, headquartered in Germany, under the name Siemens AG, which is one of the largest companies in the world.

17. This Court has subject matter jurisdiction over the claims asserted herein pursuant to the FCA, 31 U.S.C. § 3729 *et seq.*, and 28 U.S.C. §§ 1331.

18. Venue is proper in this judicial district pursuant to 31 U.S.C. § 3732(a), which provides that an action may be brought in any judicial district in which any one defendant may be found, resides, transacts business, or in which any act proscribed by the FCA occurred.

III. LEGAL BACKGROUND

The False Claims Act

19. The FCA prohibits knowingly presenting or causing to be presented to the federal Government a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1)(A). The FCA further prohibits knowingly making, using, causing to be made or used a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B). Moreover, any person who conspires to commit a violation of the FCA is also liable. 31 U.S.C. § 3729(a)(1)(C).

Small Business and SDVOSB Programs

20. In order to aid and encourage the growth and development of small businesses, Congress has established a Government-wide goal that 23% of government contracts be awarded to small businesses. Within this framework, Congress has established further subsets or categories of small businesses, and specific goals for contract awards to small business within these special categories, *e.g.*, 5% of government contracts awarded to Small Disadvantaged Businesses ("SDBs"), 5% to Women-Owned Small Businesses ("WOSBs"), 3% to Historically Underutilized Business Zone Small Businesses ("HUBZone") – and 3% to SDVOSBs. The U.S. Small Business Administration ("SBA") maintains statistics that track how successful each department and agency has been in meeting these goals.

21. To further these socioeconomic goals, the Government uses Set-Asides and preferential programs designed to encourage small businesses, including SDBs, WOSBs, HUBZone concerns, and SDVOSBs, to obtain and perform government contracts. These Set Asides specifically restrict competitive procurements to small businesses exclusively. Only businesses that are within the prescribed size standards for the supplies or services to be provided are considered "small" for the purpose of being allowed to bid on small business set-asides.[1] Bidders or offerors that exceed the applicable size standards for a particular Small Business Set-Aside are, by definition, nonresponsive and their bids or proposals will be rejected, effectively barring them from bidding on the contract.

22. The Veterans Entrepreneurship and Small Business Development Act of 1999 established an annual Government-wide goal that at least 3 percent of the total value of all prime contract and subcontract awards should be awarded to SDVOSBs. 15 U.S.C. § 644(g).

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[1] The U.S. Small Business Administration ("SBA") uses the North American Industry Classification Systems ("NAICS") as a basis for its size standards. When the Federal government intends to acquire goods or services, it identifies the NAICS code that describes the principal purpose of that procurement. The NAICS classifies business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. economy. The NAICS industry codes define establishments based on the activities in which they are primarily engaged. NAICS codes are also used for administrative, contracting, and tax purposes. NAICS is production oriented (not product oriented) and categorizes businesses with others that have similar methods of production.

23. The Veterans Benefit Act of 2003 added a contracting mechanism to enable government agencies to meet the three percent (3%) contracting goal. 15 U.S.C. § 657f. The Act permits a contracting officer to award a contract to a SDVOSB company on a "sole-source basis" (which means that the company automatically receives an award of a contract since there is no competition at all) to any small business concern owned and controlled by a service disabled veteran if: (1) the concern is determined to be a responsible contractor with respect to performance of such contract opportunity and the contracting officer does not have a reasonable expectation that two or more small business concerns owned and controlled by service-disabled veterans will submit offers for the contracting opportunity; (2) the anticipated award price of the contract (including options) will not exceed — (A) $5,000,000, in the case of a contract opportunity assigned a standard industrial classification code for manufacturing; or (B) $3,000,000, in the case of any other contract opportunity; and (3) in the estimation of the contracting officer, the contract award can be made at a fair and reasonable price. 15 U.S.C. § 657f(a).

24. The Federal Government has shown continued support for giving preferred status to SDVOSBs, in particular, in Government contracting, and has implemented, through executive orders, strategies to achieve the goal of honoring

the extraordinary service that United States veterans provided this nation. Executive Order No. 13360 (Oct. 21, 2004).

25. In a June 16, 2016 opinion, the Supreme Court unanimously held that small business contracting Set-Asides imposed by the Veterans Benefits, Healthcare and Information Technology Act of 2006 (codified at 38 U.S.C. § 8127) are mandatory, apply even when the VA has already met its annual small business subcontracting goals, and extend to Federal Supply Schedule purchase orders. *See Kingdomware Techs. V. United States*, No. 14-916, 136 S.Ct. 1969 (June 16, 2016).

26. In statutes, executive orders, and judicial opinions, all three branches of the Government have clearly spoken and taken steps to ensure that government contracts be set aside for, and awarded to, small businesses, especially those owned and controlled by veterans and service disabled veterans. Where, in order to comply with and fulfill the priorities expressed in these mandates, Government agencies have set aside and/or awarded contracts on the basis of, or taking into account, the company's status as a SDVOSB and Veteran-Owned Small Businesses ("VOSB"), a contractor's representation (or misrepresentation) about its status as a SDVOSB or VOSB, and, therefore, its compliance with [this] statutory, regulatory, or contractual requirement is material to the Government's decision to award the contract.

27. As part of its implementation of this important objective, the Government also has specified through regulations the requirements for a small

business seeking to be classified as a SDVOSB in a given contract procurement. In order to be certified as a SDOVSB, an entity must meet the following criteria:

- The Service Disabled Veteran ("SDV") must have a service-connected disability that has been determined by the Department of Veterans Affairs or Department of Defense, 15 U.S.C. § 632(q);

- The SDVOSB must be "small" under the North American Industry Classification System (NAICS) code assigned to the procurement;

- The Service Disabled Veteran must unconditionally own 51% of the SDVOSB;

- The Service Disabled Veteran must control the management and daily operations of the SDVOSB; and

- The Service Disabled Veteran must hold the highest officer position in the SDVOSB.

28. The Government also has specified through regulations the performance requirements that a SDVOSB must satisfy in order to be able to perform a contract awarded under an SDVOSB Set Aside. The SDOVSB must comply with certain limitations on subcontracting ("LOS") set forth at 13 C.F.R. § 125.6 (pre-June 30, 2016 Amendment):

- In the case of a contract for services, perform at least 50 percent of the cost of the contract incurred for personnel with its own employees; or

- In the case of a contract for supplies, perform at least 50 percent of the cost of manufacturing the supplies or products, not including the cost of materials.

29. Furthermore, as of June 30, 2016, a SDVOSB awarded a contract under the SDVOSB Set Aside also must comply with the new LOS 13 C.F.R. § 125.6(a), which requires that:

- In the case of a contract for services (except construction), the SDVOSB cannot pay more than fifty (50) percent of the amount paid to it by the Government to a subcontractor that is not similarly situated. 13 C.F.R. § 125.6(a)(1).
- In the case of a contract for supplies (other than from a non-manufacturer of such supplies), the SDVOSB cannot pay more than fifty (50) percent of the amount paid to it by the Government to a subcontractor that is not similarly situated. Costs of materials are excluded and not considered to be subcontracted, 13 C.F.R. § 125.6(a)(2)(i).

30. A similarly situated entity is a subcontractor with the same "small business program status as the prime contractor." Thus, for a SDVOSB prime contractor, a similarly situated subcontractor is a self-certified SDVOSB. In addition to sharing the same small business program status as the prime contractor, a similarly situated entity must also be small pursuant to the NAICS code that the prime contractor assigned to the subcontract that the subcontractor will perform. 13 C.F.R. § 125.1.

31. In the case of a contract for supplies valued at more than $25,000, where the SDVOSB is not the manufacturer of such supplies or performs less than fifty (50) percent of the cost of manufacturing the supplies, the SDVOSB may perform under the contract only if the SDVOSB partners with another U.S. based company which is "small" under the applicable NAICS code. 13 C.F.R. §125.6(b)(4).

32. If a subcontractor performs the "primary and vital requirements" of a contract, the contractor and its subcontractor will be treated together as a joint-venture. If, however, the prime contractor is unduly reliant on the subcontractor, the two businesses can no longer be classified as "small" under the applicable NAICS code, and the SDVOSB may not continue to certify as "small" for that contract or for any task order under that contract. 13 C.F.R. § 121.103(h)(3).

33. Applicants bidding on contracts under a SDVOSB Set-Aside must be registered as a SDVOSB in the VetBiz database in order to bid on or perform contracts for VA, and must certify to their SDVOSB status, whenever they submit a bid, proposal, application or offer for a federal grant, contract, subcontract, cooperative agreement, or cooperative research and development agreement reserved, set aside, or otherwise classified as intended for award to SDVOSBs. 13 C.F.R. § 121.108. Certifying that the applicant who will perform the contract is a SDVOSB goes "to the very essence of the bargain" that the Government is making in establishing the contract as a SDVOSB Set-Aside contract.

34. Similarly, SDVOSB companies that submit claims for payment under a SDVOSB Set-Aside contract must certify that they have complied with the regulations establishing the performance requirements for a SDVOSB contractor as described in ¶¶ 27-32, above. Certifying that the contract has been performed by the SDVOSB in compliance with the regulations the Government has established for

performance of an SDVOSB contract also goes "to the very essence of the bargain" that the Government made in establishing the contract as a SDVOSB Set-Aside contract.

35. Compliance with the regulations described in the preceding paragraphs, and certifications of compliance with these regulations, are material to the Government's decisions to award contracts to SDVOSB companies, and are material to the Government's decision to pay the claims submitted under these Set-Aside contracts.

NUCLEAR PHARMACEUTICAL REGULATIONS AND REQUIREMENTS

36. Nuclear medicine refers to medicine (a pharmaceutical) that is attached to a small quantity of radioactive material (a radioisotope). This combination is referred to as a "radiopharmaceutical," or "nuclear pharmaceutical."

37. Radiopharmaceuticals target specific organs or cellular receptors, while external detectors capture the radiation emitted from the radiopharmaceutical as it moves through the body in order to generate an image. Diagnosis is based on the way the body is known to handle substances in the healthy state versus a diseased state.

38. Radiopharmaceuticals, or nuclear pharmaceuticals, are highly regulated by multiple federal, state, and local agencies. The Nuclear Regulatory Commission

("NRC") has authority to license and regulate the possession, use, and disposal of nuclear by-product materials, including nuclear pharmaceuticals. The NRC licenses and regulates the use of nuclear by-product materials directly in twenty-one (21) states, and has transferred that authority to state regulatory agencies in twenty-nine (29) states ("the Agreement States"). Thus, under the current regulatory scheme, either the NRC or an Agreement State agency regulates the production, distribution and use of radiopharmaceuticals in a given locale, including by licensing nuclear pharmacists.

39. Individual nuclear pharmacists must first be licensed by their state boards of medicine and pharmacy before they can apply for authorization from the NRC or from an Agreement State agency to produce, distribute or use nuclear pharmaceuticals as a nuclear pharmacist.

40. In order to be licensed by the NRC or an Agreement State agency as a nuclear pharmacist, a pharmacist must:

> (a)(1) have graduated from an accredited pharmacy program; (2) hold a current, active license to practice pharmacy; (3) have acquired at least 4000 hours of training/experience in nuclear pharmacy practice; and (4) pass an examination in nuclear pharmacy; ***or***
>
> (b)(1)(i) have completed 700 hours in a structured education program consisting of 200 hours of classroom and laboratory training in (A) radiation physics and instrumentation; (B) radiation protection; (C) mathematics pertaining to the use and measurement of radioactivity;

> (D) chemistry of byproduct material for medical use; and (E) radiation biology; and (ii) supervised practical experience in a nuclear pharmacy involving (A) shipping, receiving and performing radiation surveys; (B) using and performing checks for proper operation of instruments; (C) calculating, assaying, and safely preparing dosages for patients; (D) using administrative controls to avoid medical events in the administration of byproduct material; and (E) using procedures to prevent or minimize radioactive contamination; and (2) obtained written attestation from a preceptor authorized nuclear pharmacist that the requirements have been met.

10 C.F.R. § 35.55.

41. In order to provide radiopharmaceuticals to the Government, a provider must be licensed, either by the NRC and/or by the Agreement State, to produce, distribute and use radiopharmaceuticals for human administration.

42. Agreement States have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant, other than a Federal agency or Federally recognized Indian tribe, who wishes to possess or use licensed material in one of these Agreement States must contact the responsible officials in that State for guidance on preparing an application. These applications must be filed with State officials, not with the NRC.

43. Eight of the ten contracts for radiopharmaceuticals that were awarded to TrillaMed, were awarded in Agreement States, including Arizona, Oregon,

Washington, Texas, Florida, and Louisiana; the two contracts for radiopharmaceuticals that were awarded to TrillaMed in Michigan are governed by the NRC.

44. Radiopharmaceuticals are regulated, not only by the NRC and the Agreement States, but also by the U.S. Food and Drug Administration ("FDA"). On December 11, 2011, FDA established requirements in 21 C.F.R. Part 212 for the manufacturing of PET radiopharmaceuticals[2] in accordance with Current Good Manufacturing Practices ("cGMP") which require firms manufacturing and distributing these drugs to submit either a New Drug Approval ("NDA") or Amended Drug Approval ("ADA") to the FDA for approval. All other products (non-PET products such as Tc99m Myoview or Tc99m Sestamibi) are inspected for cGMP compliance by the FDA at the manufacturing site.

45. The certification that an applicant/bidder is licensed to sell, handle, and distribute nuclear pharmaceuticals is not only material to, but an essential requirement in, the Government's decision to award a contract for radiopharmaceuticals. The certification that a contractor, especially a contractor holding itself out as able to perform a contract for radiopharmaceuticals, has

[2] Positron emission tomography ("PET") is a nuclear medicine, functional imaging technique that is used to observe metabolic processes in the body. The system detects pairs of gamma rays emitted indirectly by a positron-emitting radionuclide (tracer), which is introduced into the body on a biologically active molecule.

performed the contract in accordance with the licensing and performance requirements in the contract and regulations also is material to the Government's decision to pay the claims submitted under the contract.

IV. STATEMENT OF FACTS

Material False and Fraudulent Statements in Bidding for Radiopharmaceutical Contracts That the Government Has Set Aside for SDVOSBs

46. TrillaMed has obtained at least ten contracts for the purchase of certain radiopharmaceuticals and related services in Government-owned and operated healthcare facilities.

47. The ten radiopharmaceutical contracts awarded to TrillaMed include 36C248-18-P-0025, VA248-17-D-0066, VA248-17-P-2983, VA258-15-D0091, VA260-16-P-0454, VA260-16-P-4873, VA-260-17-D-0046, VA260-16-P-1429, W81K00-15-A-0034, and one contract, VA156-17-F-1806, in the State of Washington.

48. TrillaMed is not licensed by the NRC or by any Agreement State (including the State of Washington) to possess, use, process, export, manufacture, or import nuclear materials and waste, to handle certain aspects of their transportation, or to conduct radiation safety programs for the protection of their employees, the public, or the environment.

49. TrillaMed also is not licensed to manufacture or handle radiopharmaceuticals or licensed to operate as a nuclear pharmacy or PET pharmaceutical manufacturer under the FDA current Good Manufacturing Practices (cGMP).

50. As previously described in fn. 1, *supra,* the North American Industry Classification Systems ("NAICS") industry codes define establishments based on the activities in which they are primarily engaged. Although TrillaMed has identified more than forty-four NAICS codes in its U.S. General Services Administration's ("GSA") System for Award Management ("SAM") registration, under which it purports to do business, *it has not included the NAICS code used for nuclear pharmaceuticals (325412) among its business activities.* As a result, TrillaMed is not even listed in SAM as a possible manufacturer or provider of nuclear pharmaceuticals.

51. Thus, TrillaMed was not, and knew that it was not, eligible to apply for, or in a position to perform, contracts for radiopharmaceuticals, when it bid on and won at least ten radiopharmaceutical contracts, including contract awards that took into account and considered its SDVOSB status. .

52. On at least two occasions in 2015, TrillaMed contacted a UPPI Member nuclear pharmacy and offered to work together to win SDVOSB Set Asides for radiopharmaceuticals. In both instances, TrillaMed proposed that TrillaMed would

bid on (and win) the contract as a SDVOSB; the UPPI member nuclear pharmacy would manufacture and deliver the radiopharmaceuticals to the Government agency site as it normally would; TrillaMed would bill the customer, *i.e.*, the Government, as the prime contractor, and the UPPI member would, in turn, bill TrillaMed. TrillaMed would receive a percentage, expressed as a markup on the contract price, as its fee. In one instance, a TrillaMed representative stated, "This arrangement has worked seamlessly with PETNET." In another instance, a TrillaMed representative told the UPPI Member that it had recently signed on with PETNET (which supplies HEU pharmaceuticals), but needed a LEU pharmacy to help win government contracts for LEU pharmaceuticals.

53. PETNET advertises that it operates the largest network of PET radiopharmacies, with over fifty (50) locations worldwide, and is engaged in the manufacturing and distribution of PET radiopharmaceuticals to hospitals, clinics, and research facilities. PETNET and Siemens Medical Solutions USA, Inc. are part of the network of companies, headquartered in Germany, under the name Siemens AG, which is one of the largest companies in the world.

54. PETNET, which did not bid on, and was not awarded, the contracts at issue, and was neither eligible for, nor entitled to receive, any benefits under SDVOSB Set-Asides, sole source, or simplified acquisition awards, used

TrillaMed's status as a SDVOSB to hide the fact that the actual bidder (and awardee) was not a SDVOSB, but a subsidiary of one of the largest companies in the world.

55. TrillaMed and PETNET entered an agreement under which TrillaMed would bid on contracts for nuclear pharmaceuticals, PETNET would perform the contracts, including manufacturing, processing, providing, and servicing the use of the radiopharmaceuticals, and TrillaMed, as the ostensible awardee, would submit the claims for payment under the contract in exchange for a percentage of the contract price.

56. From 2010 to the present, TrillaMed has solicited and been awarded at least ten (10) contracts (Contract ID Numbers: 36C248-18-P-0025, VA248-17-D-0066, VA248-17-P-2983, VA258-15-D0091, VA260-16-P-0454, VA260-16-P-4873, VA-260-17-D-0046, VA260-16-P-1429, W81K00-15-A-0034 and VA156-17-F-1806 in addition to the multi-year contract options and extensions applicable to some contracts) to provide radiopharmaceuticals to various Government agencies, including the VA, that it cannot perform. The facilities serviced under these contracts are located in Arizona, Oregon, Washington, Florida, Michigan, Louisiana and Texas.

57. The total value of the ten nuclear pharmaceutical contracts fraudulently awarded to TrillaMed is in excess of thirty-five million dollars ($35,000,000).

58. At least three of these contracts were awarded in a simplified acquisition procedure based on TrillaMed's SDVOSB status.

Material False and Fraudulent Representations in Claims Submitted Under the Fraudulently Obtained Contracts

59. Other than bidding on and obtaining the contracts as a SDVOSB, TrillaMed's role was to submit the claims for payment in order to make it appear that TrillaMed had performed the contract and to conceal that the contract had actually been performed by PETNET.

60. TrillaMed is not licensed to manufacture or handle radiopharmaceuticals or licensed to operate as a nuclear pharmacy or as a PET pharmaceutical manufacturer under the FDA's current Good Manufacturing Practices (cGMPs), and, as a result, TrillaMed has falsely certified to the Government that it is licensed to possess, use, process, export, manufacture, and import nuclear materials and waste and/or handle certain aspects of their transportation in accordance with NRC and Federal Regulations, State Boards of Pharmacy and/or cGMPs.

61. TrillaMed does not maintain the proper facilities, staff, or expertise to produce, manufacture, transport, or provide radiopharmaceuticals in accordance with NRC and Federal Regulations, State Boards of Pharmacy and/or cGMP. In

other words, TrillaMed could not perform its obligations under the contracts on its own.

62. TrillaMed did not and could not have performed at least fifty (50) percent of the cost of the contract incurred for personnel with its own employees, and did not and could not have performed at least fifty (50) percent of the cost of manufacturing the supplies or products.

63. The contracts were not performed at all, or, at a minimum, were not performed in compliance with the performance standards for SDVOSB Set Asides, by TrillaMed. The contracts were performed by PETNET, which was in violation of the terms under which the contract was awarded and in violation of the regulations governing how the contract was to be performed.

64. For all claims for payment submitted after June 30, 2016 pursuant to the fraudulently awarded contracts, PETNET was not "similarly situated" much less properly "small" for the NAICS code assigned to the contracts which were performed in violation of the LOS.

65. TrillaMed and PETNET knowingly submitted, caused to be submitted, and conspired to submit false claims for payment to the Government, that included false and fraudulent certifications to the effect that TrillaMed had performed the contract as a SDVOSB, when, in fact, the contract was performed in whole or largely by PETNET.

66. TrillaMed and PETNET knowingly submitted, caused to be submitted, and conspired to submit false claims for payment to the Government, that included false and fraudulent certifications to the effect that TrillaMed had complied with the regulations governing the handling of nuclear pharmaceuticals, when, in fact, TrillaMed had not performed these functions, and could not have certified to that effect.

The Requirements Were Material to the Government's Decisions to Award the Contracts and Material to the Government's Decisions to Pay Claims Submitted Under the Contracts

67. Where, in order to encourage small businesses owned by veterans and service-disabled veterans, the Government explicitly intended that preferences be given to small businesses, including SDVOSBs, and Defendants represented and caused to be represented that TrillaMed was a SDVOSB licensed to provide nuclear pharmaceuticals, and omitted to state that TrillaMed was not licensed to provide nuclear pharmaceuticals or that the contract would, in fact, be performed by another, non-SDVOSB company, the Defendants' misrepresentations and omissions were material to the Government's decision to award the contracts for nuclear pharmaceuticals to TrillaMed.

68. Where, in order to implement its goals of aiding small businesses owned by veterans and service-disabled veterans, the Government has established regulations governing how contracts awarded under these Set Asides are to be

performed, and where Defendants have represented and caused to be represented that TrillaMed complied with these regulations, and omitted to state that the contract was performed by PETNET or that the contract was not performed in compliance with the conditions for performance specified in the regulations, the Defendants' misrepresentations and omissions were material to the Government's decision to pay the claims submitted under the SDVOSB Set Aside contracts.

69. Where, in order to protect the public health and safety, the Government has established strict regulations and requirements for the handling of nuclear materials, and where Defendants have represented and caused to be represented that TrillaMed complied with these regulations, and omitted to mention that TrillaMed was not licensed to handle nuclear materials and that any certification by TrillaMed concerning the handling of nuclear materials was, therefore, false and misleading, the Defendants' misrepresentations and omissions were material to the Government's decision to pay claims under the contracts for nuclear pharmaceuticals.

70. Where, as described above and *supra*, the Government has clearly expressed its purpose and intent to encourage small business and businesses owned by veterans and service-disabled veterans, in particular[3], and where the Government

[3]A waiver from the LOS is possible only if the Contracting Officer has determined through market research that there is no small business manufacturer who could perform the contract - and– in fact, as UPPI's membership demonstrates, there are

has enacted strict requirements for the handling of nuclear pharmaceuticals, any contracting officer who may have known of the circumstances under which these contracts were performed acted contrary to authority, and/or without authority either to award the contracts to TrillaMed or to approve the claims for payment under the contracts.

V. COUNT ONE (VIOLATIONS OF THE FALSE CLAIMS ACT 31 U.S.C. § 3729)

71. Relator incorporates by reference the paragraphs above as if fully set forth herein.

72. Defendants have violated the FCA by knowingly presenting, or causing to be presented, false and fraudulent claims for payment or approval to the Government for goods and services relating to the provision of radiopharmaceuticals.

73. In particular, during the contract bidding process for the supply of radiopharmaceutical to Government agencies, including the VA, Defendants made and caused to be made to the Government false statements, including by representing that TrillaMed could perform the contracts at issue and that it would perform these contracts in accordance with the applicable rules and regulations, including

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numerous small business radiopharmacies licensed to manufacture, produce, market, sell, and distribute nuclear pharmaceuticals.

requirements that the contractor/TrillaMed be licensed to manufacture and handle radiopharmaceuticals, which TrillaMed is not.

74. In addition, Defendants knowingly made, used, and caused to be made and used, false records and statements that were material to the Government's decisions to pay TrillaMed's claims for reimbursement, including false representations that the contracts awarded to TrillaMed were actually performed by TrillaMed in accordance with the applicable rules and regulations, when, in fact, PETNET performed all, or nearly all, of TrillaMed's obligations under these contracts in violation of federal law, rules, and regulations, including those applicable to the Small Business Set-Asides Program and others identified above.

75. The contracts for radiopharmaceuticals would not have been awarded to TrillaMed if the Government had known that TrillaMed was not licensed to provide radiopharmaceuticals, that TrillaMed was not listed as a supplier under the relevant NAICS code, or that TrillaMed was, in fact, bidding in place of another contractor/PETNET.

76. The Government would not have paid TrillaMed's claims for reimbursement under these contracts if the Government had known that TrillaMed had not performed these contracts as required by the regulations governing SDVOSB contracts, where the contracts had, in fact, been awarded to TrillaMed on that basis and in order to serve the government's purpose in creating the program,

and that any certification by TrillaMed regarding the handling of nuclear pharmaceuticals would have been meaningless since TrillaMed did not and could not handle nuclear pharmaceuticals.

77. Defendants conspired to violate the FCA.

78. The Government has paid out federal funds to Defendants based on their fraudulent conduct and is obligated to pay out more federal funds in the future.

79. Based on the foregoing, the Government has suffered damages, to be determined at trial, as a result.

VII. PRAYER FOR RELIEF

WHEREFORE, Relators request that judgment be entered in Plaintiff's against Defendants as follows:

(a) Pursuant to Count One, for treble the amount of damages incurred by the Government, in an amount to be determined at trial, and penalty of $11,000 for each false claim submitted or caused to be submitted, each record or statement made, used, presented or caused to be made, by Defendants;

(b) Awarding Relators their relators' share pursuant to 31 U.S.C. § 3730(d)(1) or (2);

(c) Awarding Relators costs and attorney's fees pursuant to 31 U.S.C. § 3730; and

(d) Awarding such other relief as is appropriate under the law.

Respectfully submitted, this 28th day of November 2017.

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VIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, UPPI hereby demands a jury trial.

Respectfully submitted this 28th day of November, 2017.

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